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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/995,303	11/27/2001	Robert C. Beck	2446	1374

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Beck & Tysver, P.L.L.C.  
2900 Thomas Avenue S., Suite 100  
Minneapolis, MN 55416

EXAMINER

DESANTO, MATTHEW F

ART UNIT PAPER NUMBER

3763

DATE MAILED: 01/16/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/995,303

Applicant(s)

BECK, ROBERT C. *MF*

Examiner

Matthew F DeSanto

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 10 December 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 7-9 and 18-27 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_ 6) ☐ Other: \_\_\_\_\_

**DETAILED ACTION**

***Election/Restrictions***

1. Applicant's election without traverse of Group II, the method claims, and Species H, Figure 13 in Paper No. 5 is acknowledged.
2. Claims 1-6 and 10-17 withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected Group and Species, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 5.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 7-9, 18-27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
4. Claim 7 recites the limitation "therapy balloon for delivering treatment" in claim 7. There is insufficient antecedent basis for this limitation in the claim. It is unclear to the examiner if the Applicant means the balloon with stent is the "therapy balloon." Please clarify.
5. Claims 8-9 and 18-27 are rejected because they are dependent on the independent claim.

***Claim Rejections - 35 USC § 102***

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

7. Claims 7-9, 18, 25, and 26 are rejected under 35 U.S.C. 102(b) as being anticipated by Simpson et al. (UPSN 5462529).

Simpson et al. discloses inserting and advancing a sheath having a discharge lumen to a location in the vessel said delivery sheath discharge lumen coupled to a collection vessel, inserting and advancing an interventional device to a treatment location, said interventional device of type having; a therapy balloon for delivering treatment, and a gap for introducing a primary fluid flow in said vessel, said gap located distal of said therapy balloon; injecting fluid out of said gap to promote retrograde flow into said discharge lumen. (Figures 1, 7, 8, 9, 10 and entire reference)

As to claim 18, wherein said injection is carried out while moving said interventional device in said vessel with respect to said delivery sheath. (Column 6, line 22 – Column 7, line 14 and Column 9 lines 20-65)

As to claim 25 and 26, wherein the therapy balloon provides angioplasty therapy, or therapy balloon provides stent placement therapy. (Column 7, lines 31-51)

As to claim 9, wherein said fluid is injection at a first injection pressure above the blood pressure in the vessel and expands to second exhaust pressure in said delivery catheter where said exhaust pressure is above said blood pressure, establishing a pressure gradient in said discharge lumen and promoting flow from said gap to said discharge lumen. (Column 6, line 22 – Column 7, line 14 and Column 9 lines 20-65)

8. Claims 7-9, 18-27 are rejected under 35 U.S.C. 102(b) as being anticipated by Neracher (5135482).

Neracher discloses inserting and advancing a sheath having a discharge lumen to a location in the vessel said delivery sheath discharge lumen coupled to a collection vessel, inserting and advancing an interventional device to a treatment location, said interventional device of type having; a therapy balloon for delivering treatment, and a gap for introducing a primary fluid flow in said vessel, said gap located distal of said therapy balloon; injecting fluid out of said gap to promote retrograde flow into said discharge lumen. (Figures 1, 3, 4, 10, 11, 12, 13, and entire reference)

As to claim 18, wherein said injection is carried out while moving said interventional device in said vessel with respect to said delivery sheath. (Figure 4, 12, 13 and entire reference)

As to claim 25 and 26, wherein the therapy balloon provides angioplasty therapy, or therapy balloon provides stent placement therapy. (Figure 13, Column 5, line 41 – Column 6, line 18)

As to claim 9, wherein said fluid is injection at a first injection pressure above the blood pressure in the vessel and expands to second exhaust pressure in said delivery

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catheter where said exhaust pressure is above said blood pressure, establishing a pressure gradient in said discharge lumen and promoting flow from said gap to said discharge lumen. (Column 3, line 53 – Column 4, line 15)

As to claim 27, wherein said primary fluid is supplied by a supply syringe chamber and said discharge lumen is coupled to syringe vacuum chamber, and said supply syringe and vacuum syringe are operated together to couple fluid supply with discharge lumen collection. (Figure 3, entire reference)

9. Claims 7-9, and 18-27 are rejected under 35 U.S.C. 102(b) as being anticipated by Carbo et al. (USPN 5250060).

Carbo et al. discloses inserting and advancing a sheath having a discharge lumen to a location in the vessel said delivery sheath discharge lumen coupled to a collection vessel, inserting and advancing an interventional device to a treatment location, said interventional device of type having; a therapy balloon for delivering treatment, and a gap for introducing a primary fluid flow in said vessel, said gap located distal of said therapy balloon; injecting fluid out of said gap to promote retrograde flow into said discharge lumen. (Figures 1, 2, 3, 4, 5, and entire reference)

As to claim 18, wherein said injection is carried out while moving said interventional device in said vessel with respect to said delivery sheath. (Figures 1, 2, 3, 4, 5, and entire reference)

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As to claim 25 and 26, wherein the therapy balloon provides angioplasty therapy, or therapy balloon provides stent placement therapy. (Figures 1, 2, 3, 4, 5, and entire reference)

As to claim 9, wherein said fluid is injection at a first injection pressure above the blood pressure in the vessel and expands to second exhaust pressure in said delivery catheter where said exhaust pressure is above said blood pressure, establishing a pressure gradient in said discharge lumen and promoting flow from said gap to said discharge lumen. (Figures 1, 2, 3, 4, 5, and entire reference)

As to claim 27, wherein said primary fluid is supplied by a supply syringe chamber and said discharge lumen is coupled to syringe vacuum chamber, and said supply syringe and vacuum syringe are operated together to couple fluid supply with discharge lumen collection. (Figures 1, 2, 3, 4, 5, and entire reference)

10. Claims 7, 9, 25 and 26 are rejected under 35 U.S.C. 102(e) as being anticipated by Nash et al. (USPN 6080170).

Nash et al. disclose inserting and advancing a sheath having a discharge lumen to a location in the vessel said delivery sheath discharge lumen coupled to a collection vessel, inserting and advancing an interventional device to a treatment location, said interventional device of type having; a therapy balloon for delivering treatment, and a gap for introducing a primary fluid flow in said vessel, said gap located distal of said therapy balloon; injecting fluid out of said gap to promote retrograde flow into said discharge lumen. (Figure 7, 10, 11, 16, 17 and entire reference)

As to claim 18, wherein said injection is carried out while moving said interventional device in said vessel with respect to said delivery sheath. (Figure 7, 10, 11, 16, 17 and entire reference)

As to claim 25 and 26, wherein the therapy balloon provides angioplasty therapy, or therapy balloon provides stent placement therapy. (Figure 7, 10, 11, 16, 17 and entire reference)

As to claim 9, wherein said fluid is injection at a first injection pressure above the blood pressure in the vessel and expands to second exhaust pressure in said delivery catheter where said exhaust pressure is above said blood pressure, establishing a pressure gradient in said discharge lumen and promoting flow from said gap to said discharge lumen. (Figure 7, 10, 11, 16, 17 and entire reference)

As to claim 27, wherein said primary fluid is supplied by a supply syringe chamber and said discharge lumen is coupled to syringe vacuum chamber, and said supply syringe and vacuum syringe are operated together to couple fluid supply with discharge lumen collection. (Figure 7, 10, 11, 16, 17 and entire reference)

***Claim Rejections - 35 USC § 103***

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. Claims 7-9 and 18-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nash et al. or Simpson et al.



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Nash et al. or Simpson et al. disclosed the claimed invention but failed to disclose coupling the discharge lumens and the fluid supply lumen to syringes.

Nash et al. discloses the use of pumps and Simpson et al. failed to disclose any fluid transport means.

At the time of the invention it would have been obvious to one of ordinary skill in the art to couple syringes to the delivery and discharge lumens of Nash et al. or Simpson et al. because it is well known in the art to use syringes as a means for introducing fluid (irrigation) into the body as well as taking fluid out of the body (aspiration).

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Matthew F DeSanto whose telephone number is 1-703-305-3292. The examiner can normally be reached on Monday-Friday 8:30-6:00.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 1-703-308-0858.



Matthew DeSanto  
Art Unit 3763  
January 13, 2003



**MICHAEL J. HAYES**  
**PRIMARY EXAMINER**